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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,191	11/25/2005	Lawrence Rosenberg	FC 14647-35	1534
1059.	7590	10/15/2007	EXAMINER	
BERESKIN AND PARR			GITOMER, RALPH J	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/558,191	ROSENBERG, LAWRENCE
Examiner	Art Unit	
Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 31 August 2007.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-12 is/are pending in the application.  
4a) Of the above claim(s) 5-12 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-4 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_

Applicant's election with traverse of Group I, claims 1-4, in the reply filed on 8/31/07 is acknowledged. The traversal is on the ground(s) that the requirements regarding product/process are not met. This is not found persuasive because the restriction requirement was made under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

The claimed method has two parts, growing pancreatic cells in a specific manner and then testing agents to induce differentiation into islet cells.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Roberts.

Roberts (6,436,704) entitled "Human Pancreatic Epithelial Progenitor Cells and Methods of Isolation of Use Thereof" teaches in column 3 line 39, human pancreatic cells were grown in F12/DMEM medium. In column 8 first paragraph, the cells are cultured with cholera toxin and various growth factors. In column 9 line 32, F12/DMEM is the growth medium. In column 10 line 12, epidermal growth factor is included in the medium. In column 12 last two paragraphs, the cells can be used for drug discovery. The pancreatic progenitor cells have the capacity to differentiate into endocrine cells. In

column 14 last paragraph bridging to column 15, using the cells for drug discovery where the pre-differentiated multipotent pancreatic progenitor cells are targets for drug development to promote differentiation of the cells to islet cells for treating diabetes is discussed.

All the features of the claims are taught by Roberts for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Korsgren and Oberg-Welsh in view of Bonner-Weir.

Korsgren (Upsala J Med Sci) entitled "In vitro Screening of Putative Compounds Inducing Fetal Porcine Pancreatic Beta Cell Differentiation: Implications for Cell Transplantation in Insulin Dependent Diabetes Mellitus" teaches on page 43 Table 1, the insulin excretion of fetal pancreatic cells treated with a number of substances to determine which best induced beta cell differentiation.

Oberg-Welsh (Pancreas) entitled "Effects of Certain Growth Factors on In vitro Maturation of Rat Fetal Islet Like Structures" teaches on page 334 last paragraph bridging to page 335, investigating various substances to differentiate beta cells from precursor cells. On page 336 Table 1 lists data from various substances to change insulin secretion.

The claims differ from the above references in that they do not specify the pancreatic cells are first grown on Matrigel before testing compounds to increase differentiation.

Bonner-Weir (PNAS) entitled "In vitro Cultivation of Human Islets From Expanded Ductal Tissue" teaches in the abstract, culturing the human islets with Matrigel to form 3D structures of ductal cysts with clusters of pancreatic endocrine cells budded. The cultures were stimulated with glucose. On page 7999 column 2 the medium was DMEM/F12. On page 8001 column 1 first full paragraph, keratinocyte growth factor stimulated growth.

It would have been obvious to one of ordinary skill in the art at the time of the invention to grow the cells by the method of Bonner-Weir prior to testing the cells for compounds to increase differentiation as taught by both Korsgren and Oberg-Welsh because Bonner-Weir grows the cells in order to get them to make insulin and stimulates them to do so, the same reason for the methods of the primary references. Further, both the claimed method of growing the cells and the method of determining compounds to increase differentiation are old. To combine the two methods would have been obvious because one would have more cells in which to test if one cultured the

cells prior to testing them. This concept is well known in drug testing and microbiology in general.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1(c) "potency" is queried in context. Further, it is unclear as to what is determined. And the method claim 1 lacks a correlating step to accomplish the preamble of the claim.

The abstract of the disclosure is objected to because it contains legal terminology. Correction is required. See MPEP § 608.01(b).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Vinik (WO 03/033808) teaches islet cell neogenesis.

Parikh (6,558,952) teaches treating diabetes.

Harrison (6,967,100) teaches in Example 24 column 24 effects of growth factors on pancreatic cells.

Peck (6,703,017) teaches in Example 10 column 21, analysis of factors which trigger pancreatic cell differentiation.

Rosenberg (Cell Transplantation) teaches pancreatic cell transformation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Ralph Gitomer*  
Ralph Gitomer  
Primary Examiner  
Art Unit 1657